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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,429	06/18/2001	David Chazan	01-052410US	9951
22798	7590	09/21/2004	EXAMINER	
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			GORDON, BRIAN R	
			ART UNIT	PAPER NUMBER
			1743	
DATE MAILED: 09/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/884,429	CHAZAN ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7-2-04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 46-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-27, and 32 is/are rejected.
- 7) ☒ Claim(s) 13,14,28-31 and 33-45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-45 in the reply filed on July 2, 2004 is acknowledged.

2. Claims 46-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 2, 2004-.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 610. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 210. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or

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amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6, 9, 11, 16, 19, 24, 26, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 6 it is unclear what the term "both" is referring to in the claim. Is both as in both first and second substrates or both as in both at least one channel network

and at least one port. The claim should be amended to clearly specify which elements applicant intends to indicate.

Claims 9 and 11 are product by process limitations that do not further limit the structure of the device. The process by which the device is formed is irrelevant to the structure. An equivalent structure made by another process would also meet the structural limitations of the device.

As to claim 16 it is unclear how a cavity can comprise one or more venting elements.

Claim 19 attempts to limit the device by specifying the type of materials the device is intended be used with. However; "the fluidic materials" as referred to in claim 19 has not been positive claimed as an element of the invention in claim 19 nor any other previous claim.

As to claim 24 it is unclear how a cavity can comprise a network of channels.

8. The term "regular or irregular" in claims 26 and 32 is a relative term which renders the claim indefinite. The term "regular or irregular" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The terms as directed to the spacing are one's own point of view. What spacing one may consider as regular another may consider as irregular.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Ackley et al. US 6,375,899.

Ackley et al. disclose an invention that relates generally to electronic devices for the movement of charged materials, especially charged biological materials. More particularly, it relates to microfluidic systems for the transport and/or analysis of electrically charged materials, especially biological materials including nucleic acids and biological pathogens or toxins.

The laminated structures are preferably formed by methods which permit the high yield, low cost manufacturing of high quality devices. The various holes, such as vent holes (as in claims 1-5), sample through holes and electrode through regions may be formed through any known technique consistent with the objects and goals of this invention. For example, microminiaturized drills may form holes as small as 3-8 mils, while laser drilled holes may be as small as 4 mils, or photolithographically patterned holes may be formed to substantially 1 mil. Generally, utilizing current technology, the thinnest sheets permit the formation of the smallest diameter holes. Optionally, chemical etching may be utilized to remove debris from the holes. This technique is particularly advantageous after laser drilling of holes, so as to reduce or remove previously ablated

materials. After the electrodes are patterned on the support, and various layers are fabricated, the laminated or composite structure 30 (body structure made of plural substrates as required in claims 4, 5; see figures) is adhered together. Generally, it is desirable to have minimal or no squeeze out of adhesive to avoid nonuniformity in terms of exposed electrode area. In one embodiment, relatively larger holes are first formed, and then relatively smaller holes are drilled through (through hole as required in claim 2) the larger holes. Alternately, the supports including vents and holes may be formed first, and then aligned, such as through optical alignment, prior to the setting of the adhesive.

11. Claims 1-8, 12, 15, 17, 18, 21-27, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Handique et al. US 6,130,098.

Handique et al. disclose the movement and mixing of microdroplets through microchannels is described employing microscale devices, comprising microdroplet transport channels, reaction regions, electrophoresis modules, and radiation detectors. The discrete droplets are differentially heated and propelled through etched channels. Electronic components are fabricated on the same substrate material, allowing sensors and controlling circuitry to be incorporated in the same device.

The term "Channels" is defined as are pathways (whether straight, curved, single, multiple, in a **network**, etc.) (claim 6) through a medium (e.g., silicon) that allow for movement of liquids and gasses. Channels thus can connect other components, i.e., keep components "in communication" and more particularly, "in fluidic communication" and still more particularly, "in liquid communication." Such components include, but are not limited to, gas-intake channels and gas **vents**.

The term "Substrate" as used herein refers to a material capable of containing channels and microdroplet transport channels. Examples include, but are not limited to, silicon and glass.

Following the proper hydrophobic patterning of the surface (e.g. the surface of a microdroplet transport channel), the present invention contemplates the placement of a patterned etched glass cap over the pattern on a flat surface (first and second substrates as in claim 3). The hydrophobic/hydrophilic channels thus formed can then be used to move precise nanoliter-volume liquid samples.

FIG. 2 shows a two-part approach to construction. Microchannels (100) are made in the silicon substrate (200) and the structure is bonded to a glass substrate (300). The two-part channel construction technique requires alignment and bonding processes but is amenable to a variety of substrates and channel profiles. In other words, for manufacturing purposes, the two-part approach allows for customizing one piece (i.e., the silicon with channels and reaction formats) and bonding with a standardized (non-customized) second piece, e.g., containing standard electrical pads (400) (claims 17, 18).

The patterned surfaces can also be used to control the motion of the drop. By placing a hydrophobic gas vent (70) further down the channel, one can stop the liquid microdroplet (60) after moving beyond the vent (70) (vent in fluid communication with port via channel as in claim 21). As the drop (60) passes the vent (70), the air will go out through the vent (70) and will not push the drop further.

12. Claims 1-8, 12, 15, 20-27, 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Dietz et al. US 6,552,784.

Dietz et al. disclose a cuvette cartridge for optical measurements of analytes in liquid samples. The cartridge comprises a flat, adhesive sheet having a selected thickness that defines an optical path length perpendicular to the plane of the flat sheet. A portion of the adhesive sheet is cut out to define at least one optical sample chamber of a desired length. The sample chamber is completed when the adhesive sheet is placed between and sealed to a first flat sheet and a second flat sheet. The first flat sheet contains an inlet hole and a vent hole which connect to the optical chamber. The vent hole is located at one end of the optical chamber, and the inlet hole is located at a second end of the optical chamber so that liquid can fill the sample chamber. In preferred embodiments, the cuvette cartridge contains a plurality of optical chambers each with its own inlet hole and vent hole.

Sheets 12 (first substrate body structure) and 14 (second substrate) are spaced apart from one another but adhesively secured together by an intermediate layer 16. Layer 16 has one or more discontinuities 16a which are areas where the layer 16 has been cut away or is otherwise not present. These areas provide sample zones having an optical path length corresponding to the thickness of layer 16, which for the purposes of the present explanation is preferably about 50 to about 200 microns, preferably 75 to about 175 microns and more preferably about 125 microns (microfluidics as in claim 23).

The sample zones present in the discontinuities in layer 16 are each accessed by a pair of openings present in sheet 12. One of these, inlet hole 20, is at one end or side

of the sample zone and the other, vent hole 22 (vent hole in body structure 12 as in claims 1 –2), is spaced away from it at the other end or side of the sample zone (see figures 2-3A).

The method of construction of cuvette cartridge 10 when layer 16 is itself a polymer film, involves the cutting, such as but not limited to laser, rotary or matched metal pattern die cutting, of the double-backed adhesive sheet 16 as indicated at 16a, to provide a readily removable piece 16b, having the desired contour of an optical chamber 18. Inlet hole 20 and vent hole 22 are cut into flat sheet 12, for example by punching.

Figure 2, illustrates numerous separate cavities/vent holes and ports as required in claims 20-22.

13. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Bhullar et al.US 6,451,264.

14. Bhullar discloses A sensor apparatus 10 for testing for biologically significant analytes of an applied biological fluid is shown in FIGS. 1-4, the apparatus being illustrative of the present invention. The sensor apparatus 10 is in the form of an easily disposable test strip 12 that includes a fluid inlet port 14 for receiving a biological fluid to be tested. A pattern of capillary pathways 16 (channel networks) and smaller channels 18 lead to a variety of testing sites 20. Each of the testing sites 20 includes an optical or electrochemical sensor illustrated as pair of electrodes 22 which are shown leading from a testing site 20 to an edge of the test strip 12 to be connected to a suitable testing apparatus, not shown. The variety of testing sites 20, which are connected to the inlet

port 14 by a variety of path lengths and widths, permits the sequential or simultaneous testing of a given biological fluid sample for multiple analytes, or the repeated testing of given portions of a sample for the same analyte for reliability, or to develop time variant functions of a given analyte interaction.

The apparatus 10 is shown (Figure 2) to include a capillary pathway 16 having at least one curved portion such as portion 24. The pathway curved portion 24 is defined by a base 30 shown to be a depressed region in a substrate 31 (second substrate), a curved inner wall 32 and a curved outer wall 34. The walls 32 and 34 are generally concentric about, and spaced from, a common center 33 situated at a point interior of the walls 32 and 34. The inner wall 32 and outer wall 34 are fixed to and integral with the base 30 and define the lateral boundaries of the capillary pathway 16. A lid 36, which can be transparent at least over the testing sites 20, extends at least from the inner wall 32 to the outer wall 34, and preferably over the entire substrate 31 to cover the capillary pathway 16. Air vents 35 (connecting testing sites 20 as in claim 8) can be included in the lid 36 or the substrate 31 (through either substrate as in claim 1 and 5) adjacent the testing sites 20 to permit air to escape from the apparatus as a specimen fluid is pulled into the apparatus by the capillary action.

Preferably a surface of the lid 36 (first substrate) confronting the substrate 31 carries the electrodes 22 from the various testing sites 20 to an exposed edge of the lid 36 so that the terminal ends of the electrodes 22 project from the edge of the substrate 31. The terminal ends of the electrodes are intended to connect to apparatus such as preprogrammed sensor reading apparatus designed to apply a predetermined potential

to the electrodes after a predetermined time interval following delivery of a liquid sample to the inlet port 14. Current flow through the sample can be measured to provide an indication of the presence and/or concentration of a target analyte. A preferred embodiment for the electrodes 22 is illustrated in FIG. 5 comprising a central electrode 37, which is shown to be square but could also be round or another convenient shape, and a peripheral electrode 39 substantially surrounding the central electrode 37. The electrodes 22 can be formed by standard lithography processes commonly used in the semi-conductor industry. As an alternative to the electrodes 22, the transparent character of the lid 36 at least over the testing sites 20 permits an optical sensor, not shown, to observe the sample interaction with a reagent to provide an indication of the presence and/or concentration of a target analyte.

Allowable Subject Matter

15. Claims 13-14, 28-31, 33-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach nor fairly suggest the device comprising stagnant vapor regions as required in claims 13-14; venting channels disposed along side of the microchannels as required in claims 33-34.

Jill Warden
Supervisory Patent Examiner
Technology Center 1700

Conclusion


17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Alajoki et al., Wyzgol et al., Anderson et al., Weigl et al., and Bochner discloses testing and diagnostic devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg


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